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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/540,479 | 05/10/2006 | Steffen Goletz | GULDE-63 | 4918 |

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MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

| EXAMINER | |
|---|---|
| GUSSOW, ANNE | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1643 | |

| MAIL DATE | DELIVERY MODE |
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| 01/03/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/540,479 | GOLETZ ET AL. | |
| | Examiner | Art Unit | |
| | Anne M. Gussow | 1643 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *79-83 and 85-116* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *79-83 and 85-116* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 October 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. Claims 79-83, 85, and 86 have been amended.

Claims 77, 78, and 84 have been cancelled.

Claims 87-116 have been added.

2. Claims 79-83 and 85-116 are under examination.

### *Priority*

3. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on January 23, 2003. It is noted, however, that applicant has not filed a certified copy of the priority application as required by 35 U.S.C. 119(b). The certified copy did not accompany the documents filed on October 29, 2007, which listed the certified copy as an enclosure.

Since the priority documents have not been received, the claims receive the priority date of January 23, 2004 for art rejection purposes.

### *Drawings*

4. The replacement drawings were received on October 29, 2007. These drawings are accepted.

***Objections Withdrawn***The objections to the specification are withdrawn in view of applicant's amendments and arguments.

6. The objection to claims 84-86 is withdrawn in view of applicant's amendment to the claims.

***Rejections Withdrawn***

7. The rejection of claims 82 and 83 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment to the claims.

***Rejections Maintained***

8. The rejection of claims 79-83, 85, 86 and newly added claims 87-116 under 35 U.S.C. 112, first paragraph, as lacking enablement is maintained.

The response filed on October 29, 2007 has been carefully considered but is deemed not to be fully persuasive.

The response is persuasive regarding the recognition molecule comprises all 6 CDR sequences in the amended claims.

The response states that the PTO's reliance on Freshney et al. (Culture of Animal Cells, A Manual of Basic Techniques, 1983) and Definer et al. (Bio/Technology, 1994) for the evaluation of the "state of the art" is rather misplaced insofar as the cited Freshney publication is fully twenty years before the earliest priority date of the instant application. The cited reference of Definer is fully ten years before the earliest priority date. Given the rapid technological progress made in the post-genomic era, a skilled

artisan would instantly question the applicability of such disclosure(s) for a fair and reliable estimate of the state of the art concerning Applicants' field of endeavor (see response page 30).

The response also states that decades of scientific studies, both at the basic and clinical levels, have established that in vitro studies "reasonably correlate" with their in vivo counterparts. In this regard, the Examiner is cordially invited to review the attached copy of Fiebig et al., European Journal of Cancer, 40 (2004) 802-820, showing correlation of in vitro to in vivo activity as the basis for anticancer drug discovery. There is no basis for the general allegation that "clinical correlations are generally lacking" to in vitro assays and/or cell-culture based assays (see response page 30).

In response to applicant's argument based upon the age of the references, contentions that the reference patents are old are not impressive absent a showing that the art tried and failed to solve the same problem notwithstanding its presumed knowledge of the references. See *In re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977).

In response to applicant's argument based on the correlation of in vitro data with in vivo studies, none of the compounds tested by Fiebig, et al. were antibodies or recognition molecules. Fiebig, et al teach TCA is not useful as a primary screening method (page 803, 2nd column) and that once in vivo activity is observed, TCA testing is extended to 48 hours (page 803, 2nd column). Thus, Fiebig, et al. is not suggesting that TCA is a reliable drug screening method without additional in vivo testing. Additionally, Fiebig, et al. only teach testing of drugs for treatment of cancer, there is no data

provided for the prevention, diagnosis, reducing, follow-up, or after-care of tumors. The as-filed specification has not provided evidence to support the prevention, diagnosis, reducing, follow-up, or after-care of tumors. The examples in the specification provide evidence to support the detection of glycosylated MUC-1 using the recognition molecule of the invention.

Therefore, after a fresh consideration of the claims and the evidence provided, the rejection is maintained.

9. The rejection of claims 79-82, 85, 86 and newly added claims 87-116 under 35 U.S.C. 101, as being directed to non-statutory subject matter is maintained.

The response filed on October 29, 2007 has been carefully considered but is deemed not to be persuasive. The response states that it is respectfully submitted that the discrete amino acid sequences recited in claims 87 or 95, or combinations comprising such exist in nature (see response page 26).

In response to this argument, the examiner agrees that the claimed recognition molecules could be found in nature and as such are drawn to non-statutory subject matter. Therefore after a fresh consideration of the claims and the evidence provided, the rejection is maintained.

***Conclusion***

10. No claims are allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

December 20, 2007

/Larry R. Helms/
Supervisory Patent Examiner